510(K) Summary
Identify

AUG 3 2012

General information

510(K) number: K112692
Owner's name: humediQ GmbH
Address: Bahnhofstraße 108, 82166 Gräfelfing, Germany
Phone: +49 (0) 152 22707070
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Name of contact person: Christian Hieronimi
Date: 12th Sep. 2011

Name of device: Identify
System trade name: Identify
Regulation number: 21 CFR §892.5050
Regulation name: Medical charged-particle radiation therapy system
Regulatory class: II
Product code: IYE

Predicated Devices

Product: iGuide System
Manufacturer: Medical Intelligence Medizintechnik GmbH
510(k) number: K062611
Substantial Equivalence Date: 31. Aug. 2006

Description

Identify displays position and identification information during radio therapy treatment to the user.

The system uses optical tracking of retro reflective disk markers to find the position of the patient and radiotherapy equipment and radio frequency identification (RFID) to obtain identification information from the patient and radiotherapy equipment.

The system consists of a PC, a graphical user interface, a NDI Polaris 3D tracking system, a video camera and a RFID reader.

Indications for Use

The intended use of the device is to identify the patient and patient specific accessories and to aid in the positioning of a patient during radiation therapy.

Substantially Equivalence Claim

Identify has the same intended use as the predicate device. It uses the same optical 3D tracking technology to locate the position of the patient and accessories.

In addition to the predicate device it uses RFID identification to read the ID of the patient and the accessories during radiotherapy from an RFID tag. This technology is used by systems which are not subject to FDA approval (Civco RFSuite, Xecan EMR RFID plug-in).

For a detailed discussion of the substantial equivalence see the document "Detailed Substantial Equivalence Claim".

Identify and its components are as safe and effective as the above-mentioned predicated device. It meets safety requirements, EN 60601-1: Medical Electrical Equipment – Part 1: General Requirements for Safety, UL 60601-1: Medical Electrical Equipment – Part 1: General Requirements for Safety and EN 60601-1-2:2007: Medical Electrical Equipment – Part 1-2: General Requirements for Safety. Collateral standard: Electromagnetic compatibility. It bears the CE mark in accordance to the Medical Device Directive 93/42/EEC.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Gundula Gehrmann
Director Quality & Operations
humediQ GmbH
Bahnhofstrabe 108
GRAFELFING 82166
GERMANY

AUG 3 2012

Re: K112692
Trade/Device Name: Identify
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: July 9, 2012
Received: July 12, 2012

Dear Ms. Gehrmann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): _____

Device Name: Identify

Indications for Use:

The intended use of the device is to identify the patient and patient specific accessories and to guide the positioning of patients and accessories for radiosurgery or radiotherapy procedures. The system uses optical tracking of optical markers and RFID tracking of RFID tags as the method of identifying the patient and the accessories. The system consists of an optical tracking system with optical markers and RFID tracking system including RFID tags, a RFID identification system, a computer workstation, an interlock unit, a handheld controller, Wireless LAN access points, a video camera and calibration tools.

The only location where the device is used is the radiologic diagnostic and radiation therapy department.

Prescription Use ___x____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K112692